

GAO

Report to the Chairman, Subcommittee
on Oversight and Investigations,
Committee on Energy and Commerce,
House of Representatives

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PUBLIC HEALTH

Blood Supply Generally Adequate Despite New Donor Restrictions



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Abbreviations

AABB	American Association of Blood Banks
ABC	America's Blood Centers
BSE	bovine spongiform encephalopathy
CDC	Centers for Disease Control and Prevention
DOD	Department of Defense
FDA	Food and Drug Administration
HCV	hepatitis C virus
HHS	Health and Human Services
HIV	human immunodeficiency virus
NAT	nucleic acid testing
NBDRC	National Blood Data Resource Center
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
NYBC	New York Blood Center
OBI	Oklahoma Blood Institute
OPHS	Office of Public Health Science
PHSA	Public Health Service Act
PPTA	Plasma Protein Therapeutics Association
TSE	transmissible spongiform encephalopathies
TSEAC	Transmissible Spongiform Encephalopathies Advisory Committee
vCJD	variant Creutzfeldt-Jakob Disease



United States General Accounting Office
Washington, D.C. 20548

July 22, 2002

The Honorable James C. Greenwood
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

The terrorist attacks of September 11, 2001, reminded the nation of the critical importance of a safe and adequate supply of blood for transfusions. Every year, about 8 million individuals donate roughly 14 million pints of blood, and approximately 4.5 million patients receive life-saving blood transfusions, according to the American Association of Blood Banks (AABB).¹ Efforts to understand supply and demand trends have coincided with renewed debate about ensuring the safety and availability of blood. Such concerns are evidenced in new Food and Drug Administration (FDA) guidance for organizations that collect, process, and distribute blood, which is aimed at reducing the possible risk of transmitting variant Creutzfeldt-Jakob Disease (vCJD), the human form of bovine spongiform encephalopathy (BSE), or “mad cow” disease, through transfusion. These “donor deferrals,” or exclusions, prevent individuals from giving blood if they have traveled extensively in the United Kingdom or Europe, thereby reducing the supply of donors. Adding to safety and availability concerns is the sharp rise in the cost of blood in recent years, partly the result of new measures for testing and processing donated blood to identify viruses and reduce adverse transfusion reactions. These issues, coupled with a historically sporadic monitoring of the blood supply, have led to questions about U.S. blood suppliers’ ability to respond to emergencies.²

You asked us to address the following objectives regarding the availability and safety of the U.S. blood supply:

- determine the adequacy of the current blood supply and describe recent trends in supply and demand,

¹AABB is the professional and accrediting organization for blood suppliers and transfusion services.

²In this report, we refer to organizations that collect, test, process, store, and sell blood as blood suppliers or blood banks.

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- describe blood suppliers' response to the September 11 terrorist attacks and their planning for future emergencies,
 - evaluate the potential impact of the new vCJD donor restrictions on the U.S. blood supply, and
 - describe recent changes in the price of blood.

To address these objectives, we measured supply and demand trends before and after September 11 by obtaining national data on the collection and distribution of blood from the National Blood Data Resource Center (NBDRC), a nonprofit research group, and the two major national blood suppliers—the American National Red Cross³ and America's Blood Centers (ABC). We attended FDA and Department of Health and Human Services (HHS) blood advisory committee meetings that reviewed blood suppliers' response to the September 11 terrorist attacks and interviewed management at the Red Cross and ABC to determine how much blood was collected and distributed in response to the attacks. In addition, we reviewed current scientific literature, FDA advisory committee recommendations, FDA guidelines, and blood supplier forecasts regarding the development and potential impact of the vCJD deferral policies. To analyze recent changes in the price of blood, we reviewed data from ABC and the Red Cross as well other studies of these price changes. To address the four objectives, we interviewed officials at HHS' Office of Public Health Science (OPHS); the Centers for Disease Control and Prevention (CDC) National Center of Infectious Disease; the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute; FDA's Office of Blood Research and Review; and the Department of Defense (DOD), Armed Services Blood Program Office. We conducted our work from May 2001 through June 2002 in accordance with generally accepted government auditing standards.

Results in Brief

The available data indicate that the blood supply has increased in the last 5 years and that its growth has kept pace with the rise in the demand for blood. Blood collections in the first half of 2001 were significantly greater than for the comparable period in 2000. Blood collections increased nearly 40 percent in the weeks immediately following September 11, but they have

³The American National Red Cross is referred to as the Red Cross in this report.

since returned to pre-attack levels, following the pattern of collections after earlier emergencies. Although local and temporary blood shortages occur from time to time, the inventory of blood in America's hospitals was at historically high levels before September 11 and has remained adequate through the first 5 months of 2002.

Blood suppliers received a high volume of blood donations immediately after the September 11 attacks. However, the very small amount of blood needed to treat survivors of the attacks resulted in a nationwide surplus—the supply was substantially greater than that needed for transfusions. Consequently, the number of units that passed their 42-day shelf life and were discarded in October and November 2001 was six times the number that expired in an average 2-month period earlier that year. Blood suppliers and the federal government now are reevaluating how blood is collected during and after disasters to avoid a repeat of this experience and also to ensure that enough blood is available during emergencies. A task force including members from federal agencies and the blood industry has been formed to coordinate the response in future emergencies to the need for blood. Insights from the experiences of September 11 and other disasters have led the task force to conclude that the need for blood in emergencies can be best met by maintaining an adequate and stable blood inventory at all times, rather than by increasing blood collections following a disaster.

The nation's blood supply can compensate for donors lost because of new donor restrictions designed to further reduce the risk of vCJD transmission. The increased incidence of BSE in the cattle herds in continental Europe has prompted FDA, the Red Cross, and DOD to implement more stringent donor deferral policies. Initial FDA guidance published in 2000 recommended the exclusion of individuals who had spent 6 months or more in the United Kingdom. This guidance was tightened in 2002 to exclude individuals who had spent 3 months or more in the United Kingdom and individuals who have spent a cumulative total of 5 years in European countries where there is a risk of acquiring vCJD by eating contaminated meat. FDA estimates that its new deferral policy will further reduce the risk of possible exposure to vCJD by 23 percent but will disqualify about an additional 5 percent of donors in the United States. Blood suppliers in areas with a large number of donors who have traveled to Europe, such as suppliers in urban areas, may be affected more noticeably by the new deferral guidance. Nonetheless, we found that, given the overall growth in the blood supply in recent years, U.S. blood suppliers

as a whole should be able to compensate for donor losses resulting from this change.

The average price of blood has risen over 50 percent since 1998. Although blood is primarily collected from volunteers, blood suppliers incur costs from collecting, processing, and testing donated blood. To recover these costs, suppliers sell processed blood to hospitals. Nonetheless, there is substantial variation in the prices paid by different hospitals and for different types of blood. The introduction of new blood safety measures has contributed to these price increases. For example, leukoreduction—the removal from blood of white blood cells that have been implicated in some adverse transfusion reactions—was not widespread in 1998, but most blood sold in the United States today is leukoreduced. Leukoreduction adds about \$30 to the price of a unit of blood.

We asked for comments on a draft of this report from HHS and DOD. HHS responded that it had no general comments. DOD concurred with our findings.

Background

About 90 percent of the U.S. blood supply is collected by two suppliers—the American Red Cross and independent centers affiliated with ABC. Generally, suppliers collect, test, and process blood and sell it to health care providers. FDA is responsible for ensuring the safety of the U.S. blood supply, which it does by inspecting blood collection procedures and enforcing federal regulations. Although past monitoring efforts by industry and nonprofit groups have examined supply and demand trends for blood, current efforts are focused on providing daily monitoring of hospitals' blood inventories.

Blood Collection and Use in the United States

In the United States, about 8 million volunteers donate approximately 14 million units of whole blood each year. Sixty percent of the population is eligible to donate blood, but in any given year only about 5 percent of those who are eligible actually do so.⁴ Eighty percent of donors are repeat donors. A typical donor gives blood approximately 1.6 times a year, but donors may give 6 times a year, or every 8 weeks, which is the period the

⁴To be eligible to donate, a person must be at least 17 years of age, weigh at least 110 pounds, be in good physical health, and provide a medical history.

body needs to replenish red blood cells. The Red Cross and ABC each collect about 45 percent each of the nation's blood supply, and roughly 10 percent is supplied by other independent blood centers, DOD, and hospitals that have their own blood banks.

Most hospital transfusion services purchase blood and blood components under a contract with a local supplier which describes the price and quantity of blood to be delivered. Blood suppliers use resource-sharing programs to help suppliers in high-demand areas buy blood that is not needed by the supplier that collected it. Taken together, the Red Cross, ABC, and AABB's National Blood Exchange moved about 1.4 million units of blood—over 10 percent of the nation's supply—among suppliers in 2000. In addition, the Red Cross has a nationwide inventory control system to facilitate the movement of its surplus blood.

Donated blood is tested for blood type (A, B, AB, and O) and Rh type (positive or negative).⁵ Donors with type O Rh negative blood are known as “universal donors,” since it can be given to patients of any blood type in an emergency.⁶ Donated blood is also screened for a number of diseases and other elements that could prevent its use. For example, blood is tested for red blood cell antibodies that may cause an adverse reaction in recipients and screened for hepatitis viruses B and C, human immunodeficiency viruses (HIV) 1 and 2, other viruses, and syphilis. Most U.S. blood products are now filtered to remove a class of cells known as leukocytes (white blood cells), which have been implicated in adverse transfusion reactions. Each unit of whole blood is separated into specialized components, or “products,” consisting of various types of blood cells, plasma,⁷ and special

⁵The most common blood type in the United States is O (about 45 percent of the population have this type), followed by A (40 percent), with types AB and B composing the remaining 15 percent. Approximately 84 percent of U.S. blood donors are Rh-positive.

⁶Rh-negative blood can be transfused into patients who are either Rh-negative or Rh-positive. Rh-negative patients must receive Rh-negative blood.

⁷Plasma is the liquid portion of blood containing nutrients, electrolytes, gases, albumin, clotting factors, hormones, and wastes. “Source plasma” is collected through a process called plasmapheresis that draws only the plasma portion of blood from donors. Plasma that is separated from whole blood after it is collected is known as “recovered plasma.” Each year about 1.5 million paid donors give 13 million units of plasma at commercial source plasma collection facilities. Plasma donations can be processed further into products used in burn treatment and surgery as well as therapy for patients lacking particular blood components as a result of hereditary diseases like hemophilia or immune deficiencies.

preparations of plasma. Health care facilities transfuse the resulting 26.5 million components into about 4.5 million patients per year.

Red blood cells may be stored as a liquid for up to 42 days. Blood banks maintain a supply cushion to meet the uncertain demand for blood. This means that some blood is discarded; for example, from January through August 2001, about 2 percent of the blood supply expired without being transfused. Red blood cells can also be frozen and stored for later use. The military makes extensive use of frozen blood inventories to meet wartime contingencies, maintaining stocks of frozen type O units that can be transferred into most patients regardless of their blood types. However, because freezing and thawing blood is expensive and labor intensive, civilian blood centers maintain relatively small inventories of frozen blood, primarily of rare blood types. A new device approved by FDA in May 2001 may make frozen blood more useful in the future—it can extend the shelf life of thawed, previously frozen blood from 24 hours to 14 days.⁸

⁸The automated glycerolization and deglycerolization device prepares units for freezing with the addition of glycerol, which prevents red blood cells from bursting when frozen, and removes glycerol during thawing in a closed system that ensures that the blood remains sterile.

There are several ways for hospitals to reduce the amount of blood they use. For example, one large hospital we contacted was able to save \$1 million and 10,000 units of blood over 8 years by promoting awareness of blood use among physicians and by improving how blood is ordered and used during surgeries. A recent study of blood use during neurosurgery at a large teaching hospital found that, because the hospital's system for ordering blood had not kept pace with advancements in surgical techniques, physicians ordered 5.5 times more blood than was transfused during surgery.⁹ One multifaceted approach to blood conservation is known as bloodless surgery. This practice involves the use of pharmaceuticals that stimulate the production of red blood cells,¹⁰ surgical equipment that cleans and returns lost blood to the patient, and intravenous solutions that maintain blood volume.¹¹ During a pilot study of bloodless surgery techniques, one hospital successfully used these techniques instead of blood transfusions for several hundred surgical patients.¹²

⁹D.E. Couture and others, "Blood Use in Cerebrovascular Surgery," *Stroke*, vol. 33, no. 4 (2002), pp. 994-7.

¹⁰L.T. Goodnough and others, "Transfusion Medicine: Blood Conservation," *New England Journal of Medicine*, vol. 340, no. 7 (1999), pp. 525-33.

¹¹S. Ozawa and others, "A Practical Approach to Achieving Bloodless Surgery," *Journal of the Association of Perioperative Registered Nurses*, vol. 74, no. 1 (2001), pp. 34-47.

¹²Another new technology that may augment the blood supply in the future is a device capable of collecting twice as many red blood cells from each donor, which it does by returning plasma and platelets to the donor. It has been estimated that this device could increase the overall blood supply by as much as 17 percent if fully used.

Federal Regulation of Blood

The Public Health Service Act (PHSA) and the Federal Food Drug and Cosmetic Act form the basis of the Public Health Service's authority, as enforced by FDA, to ensure the safety of blood that is collected and transfused in the United States. PHSA requires that all blood and blood components distributed in interstate commerce be licensed by FDA in order to ensure that the products are safe and effective.¹³ Under PHSA, FDA can recall blood and blood components that present an imminent or substantial hazard to public health. The licensing and regulatory standards set by FDA attempt to maintain a blood supply that is both adequate and safe. Blood suppliers routinely take safety precautions beyond those required by FDA. For example, although FDA has not required nucleic acid testing (NAT), a sophisticated test to detect HIV and hepatitis C virus (HCV), virtually all blood centers perform it.¹⁴ Similarly, FDA has not mandated universal leukoreduction, but most blood centers have adopted the practice.

¹³The pertinent provision of the PHSA is §351 (42 U.S.C. §262 (1994)).

¹⁴FDA has announced its intention to require HIV-1 and HCV NAT testing in the future. See Food and Drug Administration, *Guidance for Industry: Use of Nucleic Acid Tests on Pooled and Individual Samples from Donors of Whole Blood and Blood Components for Transfusion to Adequately and Appropriately Reduce the Risk of Transmission of HIV-1 and HCV* (Rockville, Md.: March 2002).

When suppliers violate regulations, FDA takes legal action to prevent further violations. These legal actions can result in the parties entering into consent decrees of permanent injunction to comply with all applicable blood safety rules. Several blood and plasma suppliers as well as manufacturers of blood testing supplies are currently under consent decrees for various violations. One of the most significant of these agreements now in force is with the Red Cross, which entered into a consent decree in 1993,¹⁵ after FDA discovered that the Red Cross had failed to follow its own standard operating procedures, had deficiencies in its quality control processes, and had committed other violations.¹⁶

¹⁵*United States v. American National Red Cross*, Civil Action No. 93-0949 (D.D.C.), May 12, 1993.

¹⁶In December 2001, FDA asked a federal court to hold the Red Cross in contempt for violation of the consent decree. FDA inspections found quality assurance violations at both Red Cross headquarters and at one of its regional blood banks that included incomplete labeling, the release of possibly contaminated products, and a lack of adequate quarantine and inventory controls. The case was pending as of May 16, 2002. See Department of Justice, Office of Consumer Litigation, *Memorandum in Support of Motion for Order to Show Cause Why Defendants Should Not be Held in Civil Contempt of and to Modify the Consent Decree of Permanent Injunction*, Civil Action No. 93-0949, Dec. 11, 2001.

FDA has no authority to determine the amount of blood that should be collected or to compel suppliers to make products available. However, FDA recognizes that an insufficient blood supply is a public health risk, and it can make certain recommendations within its authority under PHS and the Federal Food, Drug and Cosmetic Act, as amended, related to the availability of blood during public health emergencies. In an emergency, FDA and other HHS agencies can give advice to blood banks on prioritizing the use of blood and facilitating the shipment of existing inventory to the areas affected.¹⁷ For example, after the September 11 attacks, FDA issued emergency guidelines to speed the delivery of blood to areas affected by the attacks. The guidelines allowed donated blood to be shipped to crisis areas before NAT was completed and to allow clinical staff who were not trained in all procedures to collect blood, in order to supplement the fully trained staff.¹⁸ FDA's emergency guidelines were rescinded on September 14, 2001, upon recognition that blood supplies were more than adequate to address current needs. HHS also can purchase blood and blood components and make other arrangements to respond to threats to the safety and sufficiency of the blood supply.¹⁹

Monitoring the Blood Supply

While periodic surveys of the blood supply have been conducted for years, no data on daily, weekly, or monthly national and regional blood collections or usages were readily available to federal officials or blood suppliers until 2000. NBDRC has conducted a biennial retrospective survey of blood suppliers since 1997, and others conducted similar periodic surveys before that. NBDRC's latest comprehensive biennial survey of blood supply and usage measured all units collected and transfused in 1999. In periods between these biennial surveys, NBDRC conducts interim retrospective studies that measure the pace and number of collections. In addition, both

¹⁷See 42 U.S.C §247d (1994).

¹⁸While FDA does not currently mandate NAT testing, almost all blood industry groups perform the serological test. The guidelines stated that blood products shipped before any testing was completed must be labeled "For Emergency Use Only" and must list the tests that had not been completed. *FDA Policy Statement on Urgent Collection, Shipment and Use of Whole Blood and Blood Components for Transfusion to Address Blood Supply Needs in the Current Disaster Situation*, (Rockville, Md.: Sept. 11, 2001).

¹⁹CDC, NIH, and the Centers for Medicare and Medicaid Services all have additional responsibilities regarding the safety of the U.S. blood supply. See U.S. General Accounting Office, *Blood Supply: FDA Oversight and Remaining Issues of Safety*, GAO/PEMD-97-1 (Washington D.C.: Feb. 25, 1997).

the Red Cross and ABC have reported their annual collections from 1996 through 2001.

Both the Red Cross and ABC have taken steps recently to improve the measurement of blood collections and inventories in their own centers. For example, the Red Cross recently introduced a large-scale, centralized inventory tracking system. This system monitors blood inventories and distribution daily across all Red Cross blood centers, enabling projections of demand and potential shortages using both daily data and historic blood usage patterns. Since March 2002, the independent blood centers affiliated with ABC have participated in a less comprehensive daily inventory reporting system.²⁰

In November 1999, HHS made a commitment to improve the monitoring of the blood supply as part of its Blood Action Plan announced in 1998. As a first step, the HHS Office of the Assistant Secretary for Health and NHLBI contracted with NBDRC to provide monthly data on supply and demand trends using a statistically representative sample of 26 blood suppliers that account for about one-third of U.S. blood collections. Data from this survey in 2000 indicated that the blood inventory was stable and that blood banks were absorbing the impact of the first vCJD donor deferral better than initially expected. NHLBI terminated the NBDRC contract, and OPHS assumed support for the NBDRC data collection effort through the end of 2001. NBDRC has continued this data collection effort without public funding.

Partly to compensate for the loss of the NBDRC data, OPHS introduced its own early warning, or sentinel, system in August 2001. The system is designed to detect blood shortages that may adversely affect patient care and analyze demand trends at transfusion centers and hospitals nationwide. OPHS collects daily blood inventory and use data from 26 hospitals and three transfusion centers that account for about 10 percent of the national blood inventory. Although the hospital sample is not statistically representative, it includes both small and large hospitals in different geographic regions of the United States meant to serve as indicators of impending blood shortages. To obtain supply data, OPHS has also begun negotiations with ABC and the Red Cross to make available

²⁰See *America's Blood Centers Supply Status Report* (http://www.transfuse.org/plsql/ecat/supply_monitor_pkg.web_report).

daily supply data from their collection centers, although neither ABC nor the Red Cross has yet agreed to do so.

vCJD

First reported in 1996, vCJD is a progressive and invariably fatal neurodegenerative disease, part of broader class of diseases known as transmissible spongiform encephalopathies (TSE). As of June 2002, there were 130 individuals with confirmed or probable cases of vCJD: 122 in the United Kingdom, 6 in France, 1 in the Republic of Ireland, and 1 in Italy. It is suspected that these individuals contracted the disease from eating meat from cattle infected with BSE (mad cow disease) in the United Kingdom before 1990. Cattle herds in the United Kingdom suffered an epidemic of BSE that peaked in 1992 and subsequently declined as a result of government actions to change the composition of cattle feed. The incubation period for vCJD is long, but its precise length is not known. This makes it difficult to project how many people will ultimately become ill. The United States has one likely case of vCJD, a 22-year-old citizen of the United Kingdom living in Florida who is thought to have acquired vCJD in the United Kingdom. There have been no confirmed cases of BSE in U.S. cattle.²¹

In response to the possibility that vCJD could be transmitted through blood transfusions, in November 1999, FDA recommended deferring by April 2000 blood collections from individuals who had resided or traveled in the United Kingdom for a total of 6 months or more from 1980 through 1996.²² In recognition of the evolving BSE epidemic, FDA issued a more restrictive policy in January 2002.

The Blood Supply Generally Is Adequate

Available data indicate that both blood collections and transfusions increased substantially from 1997 through 2001. While local and temporary blood shortages have occurred periodically, the nation's blood supply generally is adequate. Although blood collections increased nearly 40 percent in the weeks immediately following September 11, they since have

²¹See U.S. General Accounting Office, *Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*, GAO-02-183 (Washington, D.C.: Jan. 25, 2002).

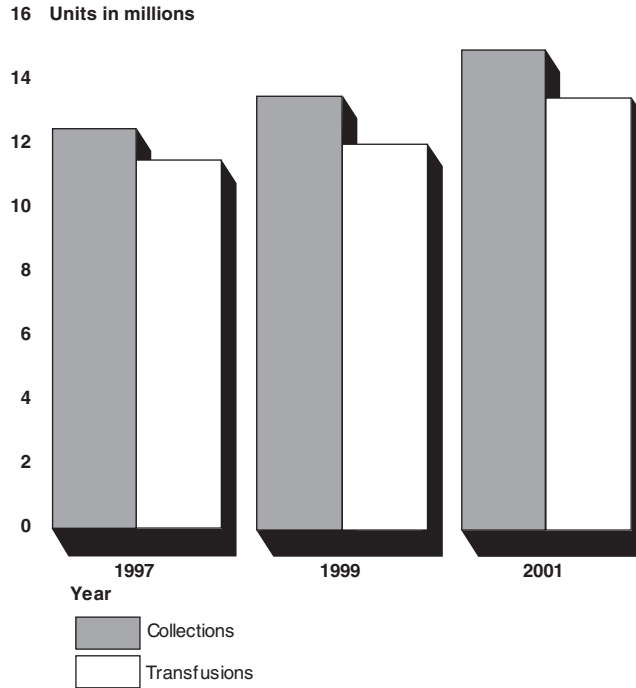
²²See U.S. General Accounting Office, *Blood Supply: Availability of Blood to Meet the Nation's Requirements*, GAO/HEHS-99-187R (Washington, D.C.: Sept. 20, 1999).

returned to pre-September 11 levels, following the pattern of collections after other emergencies. The inventory of blood in America's hospitals was at historically high levels before the surge in collections after September 11 and has remained adequate through the first 5 months of 2002.

Blood Supply and Inventory Trends Are Positive

Although no one data source has comprehensively tracked the nation's blood supply in the past, all of the sources we identified indicated that the national supply has grown in recent years and was at historically high levels before the surge in donations that occurred after September 11. Annual blood collections have increased substantially—21 percent—since 1997, according to NBDRC measurements and estimates of annual blood collections by all blood centers. (See fig. 1.) The number of units of blood donated annually increased from 12.4 million in 1997 to an estimated 15 million in 2001. (NBDRC estimated that 2001 collections would have reached 14.5 million units, 17 percent higher than in 1997, without the post-September 11 surge.) The increase in supply has kept pace with the increase in the amount of blood transfused; for example, NBDRC data indicated that the number of red cell units transfused rose 17 percent from 1997 to 2001, from 11.5 million to 13.5 million units, and the annual number of units that were not transfused remained at about 1 million units, not counting the post-September 11 surge.

Figure 1: Units of Blood Collected and Transfused, 1997-2001



Note: Collection data include allogeneic donations of whole blood and red blood cells.

Source: NBDRC.

Available data indicate that 2001 collections had risen even before the increase in donations following September 11. For example, the Red Cross reported a 2.2 percent growth in total collections for the first 7 months of 2001 over the same period in 2000. In addition, reflecting the success of a Red Cross campaign to increase donations, the number of units collected at Red Cross blood centers was 8 percent higher in July and August 2001 than the number collected during the same period in 2000. Similarly, NBDRC reported that the 26 blood suppliers included in its statistically representative national sample increased blood deliveries to transfusion centers by 5 percent in May, June, and July 2001, compared with that period in 2000.²³

²³According to NBDRC, the 26 blood centers in its survey are statistically representative of all U.S. blood centers that collect more than 25,000 units of blood annually.

The increased collections placed the inventories in America's blood banks at historically high levels just prior to the September 11 attacks. The Red Cross reported that its total red blood cell inventory was 33 percent higher in August 2001 than it was in August 2000 and that its type O inventory was 83 percent higher than it was in August 2000. The New York Blood Center (NYBC) reported that it had a 4- to 5-day supply of blood on hand in early September. On September 10, 2001, the median inventory for the hospitals in HHS's Blood Sentinel Surveillance System for all blood types stood at approximately 7 days, and for type O Rh negative blood, at 6 days.

Blood Collections Have Returned to Pre-September 11 Levels

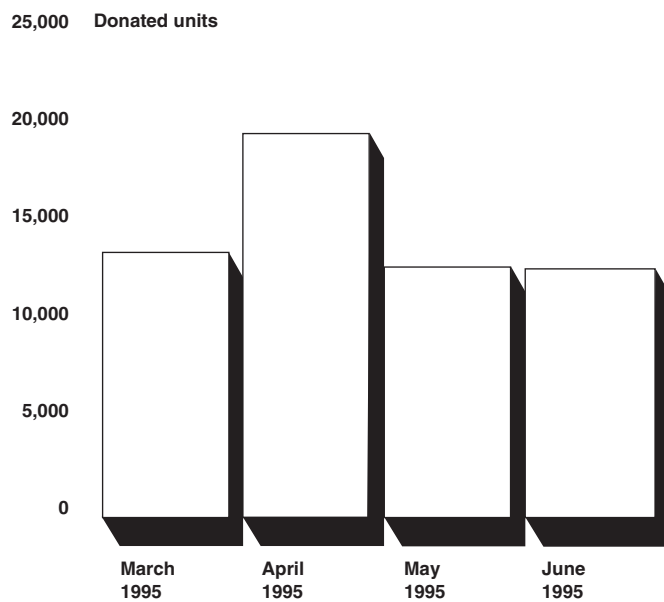
In response to the perception that blood was needed to treat victims of the terrorist attacks, Americans greatly increased their blood donations in the weeks immediately after September 11. NBDRC estimated that total blood collections in the United States were 38 percent higher in September 2001 than average monthly collections earlier in 2001. The Red Cross reported that its national blood collections during the week of September 11 more than doubled compared with the preceding weeks. However, as with previous disasters, the sharp increase in blood collections in response to September 11 did not last. While higher than usual blood collections continued for several weeks after September 11, the number of units collected had returned to the baseline level or slightly below it by the beginning of November.²⁴

The post-September 11 pattern of collections mirrors the collections after the April 19, 1995, bombing of the Edward R. Murrah Federal Building in Oklahoma City. (See figs. 2 and 3) Like the September 11 attacks, the bombing of the Murrah building was a discrete event—there were not continued attacks—and it became clear soon after the attack that a large supply of blood would not be needed for the survivors. The Oklahoma Blood Institute (OBI), the primary blood supplier for the area, recorded a nearly 45 percent increase in donations for April 1995 compared with the previous month. The spike included an increase in repeat donors and an 85 percent increase in first-time donors. But collections rapidly returned to their baseline level in May.

²⁴Because donors can only give blood every 8 weeks, large numbers of regular donors who give immediately after a disaster may skip their next planned donation, thus causing postdisaster inventory to dip below normal levels.

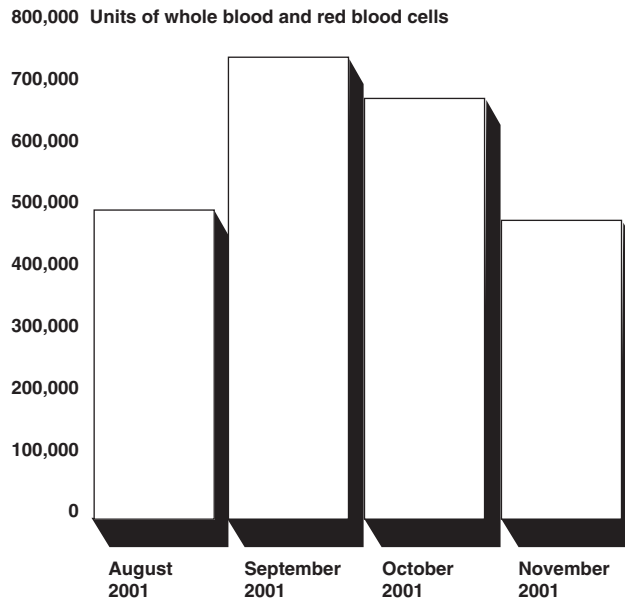
In contrast with the Oklahoma City bombing, the Persian Gulf War was accompanied by a perceived need for blood that spanned a longer period. OBI's data recorded a sustained increase in donations for 3 months beginning in November 1990, peaking in January 1991 at more than 25 percent higher than usual, and continuing through the end of the conflict in February 1991. But by March 1991, donations had returned to baseline levels.

Figure 2: Volume of Blood Collections before and after the Oklahoma City Bombing in April 1995



Source: OBI.

Figure 3: Volume of Red Cross Collections before and after the September 11th Attacks



Source: GAO calculation from Red Cross data.

The limited information available to us indicates that blood collections early in 2002 were roughly comparable to the levels immediately prior to September 11. For instance, the number of units collected in April 2002 by the 26 blood centers in NBDRC's sample was approximately equal to the number collected in August 2001. Similarly, the hospital inventories measured by HHS's Blood Sentinel Surveillance System in early May 2002 were similar to those levels measured just prior to September 11, 2001.

Blood Suppliers' Response to September 11 Attacks Has Focused Emergency Planning on Maintaining Adequate Inventory

The high volume of blood donations made immediately after September 11, and the very small amount of blood needed to treat survivors, resulted in a national surplus—supply was substantially greater than needed for transfusions. Consequently, the proportion of units that expired and were discarded in October and November 2001 was six times higher than the proportion that expired on an average 2-month period in early 2001. Blood suppliers and the federal government are reevaluating how blood is collected during and after disasters to avert the large amounts of blood that went unused and the logistical strains of collecting unneeded blood. A task force of federal and blood supply officials has been created to coordinate

blood suppliers' response to future disasters. Incorporating the lessons learned from past disasters, the task force has recommended that blood banks focus on maintaining a consistently adequate nationwide inventory in preparation for disasters and not collecting more blood after a disaster than is medically necessary.

Response of Blood Suppliers to September 11 Had Unintended Consequences

America's blood banks collected an unprecedented amount of blood in a short period after the September 11 attacks. HHS, ABC, and the Red Cross all issued requests for blood donations, although HHS and ABC quickly stopped issuing requests when it became clear that there were few survivors of the attacks and there was a limited additional need for transfusions. Many blood suppliers were reluctant to turn away potential donors, and some hospitals that did not have their own blood banks responded to the surge in volunteers by collecting blood anyway. This surge of donors stressed the collection system. Shortages in blood collecting supplies, phlebotomists (technicians trained to collect blood), and storage capacity occurred as more potential donors arrived. Long waiting lines developed because there was insufficient staff to draw blood.

Far more blood was collected immediately after September 11 than was needed by survivors or than ultimately could be absorbed by the nation's blood banks. Estimates of the number of additional units collected nationwide range from 475,000 to 572,000, and fewer than 260 units were used to treat victims of the attacks.²⁵

A portion of this additional supply went unused, expired, and was discarded. The Red Cross reported that its collections peaked from September 11 through October 14, and that 5.4 percent of the blood it collected during that time went unused and expired. ABC officials told us that its affiliated blood banks discarded approximately 4 percent of the blood they collected after September 11, although the officials cautioned that the figures reported to them by their independent centers might have underestimated the number of units that expired. NBDRC's monthly survey of a nationally representative sample of 26 blood suppliers found that a higher percentage of units were outdated. NBDRC reported that about 10 percent of the units collected in September and October by the suppliers it surveyed were outdated and discarded. This was nearly a five-

²⁵P.J. Schmidt, "Blood and Disaster--Supply and Demand," *New England Journal of Medicine*, vol. 346, no. 8 (2002), pp. 617-20.

fold increase in the proportion of units these suppliers outdated and discarded in the first 8 months of 2001—about 2 percent of their collections, on average. On the basis of NBDRC's figures, we estimate that approximately 250,000 units of blood were outdated and discarded in October and November 2001; this is nearly six times the estimated 42,000 units discarded in an average 2-month period earlier in 2001. All of these figures may underestimate the total number of expired units, since they represent expirations at blood suppliers only and do not capture units that may have expired in hospital inventories.

Increased errors in the collection process at some blood banks accompanied the surge in donations. As much as 20 percent of some blood banks' donations were collected improperly and had to be discarded, primarily because individuals had not completed the donor questionnaire correctly.²⁶ Some blood banks also suffered serious financial losses, as they incurred the costs of collecting and processing units of blood they could not sell. For example, NYBC claimed it lost from \$4 million to \$5 million and suffered a nearly three-fold increase in the number of units it had to discard when blood donated in response to the attack expired.

²⁶American Association of Blood Banks: Interorganizational Task Force on Domestic Disasters and Acts of Terrorism, *Report and Recommendations* (Bethesda, Md.: Jan. 31, 2000) http://www.aabb.org/Pressroom/In_the_News/idfddat013002.htm (downloaded on Feb 5, 2002).

Efforts to Improve Disaster Readiness Have Begun

Since September 11, federal public health agencies and blood suppliers have found fault with their responses to prior disasters and begun to plan for a more effective response to future emergencies. Through an interorganizational task force organized by AABB in late 2001, the focus has begun to shift away from increasing blood collections in an emergency to maintaining an adequate inventory of blood at all times.²⁷ This shift was prompted by the realization that a surge in blood collections following a disaster does not help victims because disaster victims rarely require many units of blood and because newly collected blood cannot be used immediately.²⁸ For example, as with September 11, only a small percentage of the additional blood collected after the Oklahoma City bombing was transfused into victims (131 units of more than 9,000 units collected). Moreover, the units used to treat victims in the hours after a disaster are those already on hand at the treating hospital or local blood bank.²⁹ It takes 2 days to completely process and test a unit of newly donated blood, so existing stores of blood must be used to treat disaster casualties. Finally, military experts and blood industry officials told us that it is unlikely a discrete disaster scenario would require more blood than is normally stored in the nation's blood inventory. They noted that large amounts of blood have not been needed in building collapses (like the September 11 attacks and the Oklahoma City bombing), nor would blood transfusions be a likely treatment for illnesses caused by a bioterrorism attack.

The AABB task force report made recommendations for the emergency preparedness of the blood supply that were adopted by the HHS Advisory Committee on Blood Safety and Availability.³⁰ The recommendations are

²⁷The AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. Members include the HHS Office of Public Health Preparedness, FDA, DOD, CDC, the Red Cross, and ABC.

²⁸P.J. Schmidt, "Blood and Disaster—Supply and Demand," pp. 617-20.

²⁹In an emergency situation, blood that has not been fully tested may be on hand and may be used in lifesaving circumstances using emergency release procedures. In such circumstances, the requesting physician must sign a statement indicating that the clinical situation is sufficiently urgent to require the release and use of blood before the completion of testing.

³⁰The Advisory Committee on Blood Safety and Availability provides advice to the Secretary of HHS and to the Assistant Secretary for Health on (1) the implications for blood safety and availability of various economic factors affecting product cost and supply, (2) definition of public health parameters around safety and availability of the blood supply, and (3) broad public health, ethical, and legal issues related to blood safety.

aimed at having federal and other organizations that are involved in the collection or use of blood coordinate their actions in an emergency. For example, the task force recommended the designation of all blood banks as suppliers of blood in an emergency and that the Assistant Secretary for Health serve as the spokesperson for all organizations involved in managing and transporting blood in an emergency. The task force also recommended that it act as the coordinating group during emergencies to assess the medical needs of victims for blood.

Both the Red Cross and ABC are independently pursuing their own plans to meet emergency and long-term needs. The Red Cross expects to increase annual collections by 9 percent during each of the next 5 years. The Red Cross also plans to implement a “strategic blood reserve” within the next 5 years using preregistered donors and a limited stock of frozen blood cells. ABC has established a “national strategic donor reserve” through which it can call on the donors it has registered, if needed.

Blood Centers Can Compensate for Donors Lost Because of New Donor Exclusion Policy

In response to the increased incidence of BSE in the cattle herds of many European countries, FDA, the Red Cross, and DOD are prohibiting blood donations from a greater proportion of individuals who have resided in countries where there is a risk of acquiring vCJD by eating contaminated meat. FDA estimates that its new deferral policy will further reduce the risk of possible exposure to vCJD by 23 percent but that it will disqualify about 5 percent of current blood donors in the United States. Nonetheless, given the overall growth in blood collections in recent years, it is likely that suppliers and others involved in blood collections, on the whole, can compensate for donor losses from the new policy.

New vCJD Donor Exclusions Are More Restrictive

In August 1999, FDA issued guidance that recommended prohibiting donations from individuals who had resided or traveled in the United Kingdom for a total of 6 months or more from 1980 through 1996, a period during which that country experienced an epidemic of BSE in cattle.³¹ In response to the detection of BSE in cattle in European herds, in January 2002 FDA issued guidance to expand this recommended exclusion to prohibit donations from individuals who had spent a cumulative 3 months in the United Kingdom from 1980 through 1996, or 5 years or more in a European country since 1980. The portion of FDA's new guidance pertaining to residents of the United Kingdom and France took effect on May 31, 2002, and the deferral of donors who have resided in other European countries will take effect on October 31, 2002. FDA's guidance exempts donors of source plasma who had resided in Europe for 5 years from 1980 through 1996, but it prohibits source plasma donations from those who had resided in the United Kingdom for at least 3 months from 1980 through 1996. The guidance also recommends indefinite deferral of source plasma donors who have spent 5 or more years cumulatively in France from 1980 to present.³²

The Red Cross and DOD have independently adopted donor deferral policies for their blood centers that are more stringent than FDA's guidance. The Red Cross excludes donors who have spent a cumulative 3 months or more in the United Kingdom or 6 months in a European country since 1980. The Red Cross policy does not exempt plasma donors because most of its plasma is recovered plasma from donors of whole blood. DOD's policy made minor modifications to FDA's new deferral criteria. The new deferral policies are described in greater detail in appendix I.

³¹FDA guidance documents are not regulations, and they do not have the force of law. In practice, however, all blood banks have treated the guidance as requirements and have implemented donor restrictions that are at least as restrictive as those recommended by FDA.

³²FDA exempted source plasma from donors who had spent time in Europe during the period indicated because plasma-derivative processing can remove the agent thought to cause vCJD and because of concerns about maintaining sufficient supplies of important plasma-derivative therapies (see app. I). Plasma derived from whole blood, however, is subject to the same restrictions as whole blood.

New vCJD Donor Exclusions Lower Potential Risk but Also Reduce the Number of Eligible Donors

Because so little is known about the etiology of vCJD, estimates of the public health benefits from blood donor exclusions related to vCJD are uncertain. It has not been established that vCJD is transmissible through blood, and no tests to diagnose vCJD or detect vCJD in blood have been developed. Nonetheless, laboratory experiments point to a theoretical risk of transmission of vCJD through blood. (See app. II for a description of scientific research on vCJD.)

FDA estimates that the additional risk reduction from the new vCJD donor deferral policies is substantially lower than the risk reduction derived from its initial deferral guidance. FDA estimates that its initial donor deferral that took effect in April 2000 reduced the amount of theoretical risk of vCJD transmission through blood transfusion in the United States by 68 percent³³ and that the expanded deferral guidance is expected to reduce total risk of donor exposure to the agent that causes vCJD by an additional 23 percent, for a total risk reduction of 91 percent. Using the same methodology, FDA estimates that the Red Cross's new donor deferral policy will decrease the total theoretical risk of exposure to the vCJD agent by 92 percent (1 percent more than FDA's donor deferral recommendations).

³³The model FDA used to estimate donor exposure to the BSE/vCJD agent assumes a linear risk related to the duration and likelihood of dietary exposure to beef from BSE-affected cattle. Compared with the United Kingdom, other European countries have experienced few vCJD cases and a lower incidence of indigenous BSE in cattle herds. For these reasons, FDA assigned a lower risk estimate to time spent in other countries. For example, FDA estimates that the risk in European nations is 1.5 percent to 5 percent of the risk in the United Kingdom. If the risk of exposure to BSE in Europe is 5 percent of the risk in the United Kingdom—at the high end of FDA's estimates—a pan-European deferral of 5 years (60 months) would be equivalent to the new 3-month deferral for cumulative travel or residence in the United Kingdom. See Food and Drug Administration, *A Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products* (Rockville, Md.: Jan. 2002).

Estimates of the percentage of current donors who would be disqualified under the new deferral policies are substantially larger than the estimated donor losses from the first vCJD donor deferrals. On the basis of data from a 1999 survey of blood donors, FDA estimates that its new deferral policy will disqualify about 5 percent of current blood donors and that the Red Cross deferral policy will disqualify about 9 percent.³⁴ On the basis of the results of a June 2001 survey of its own blood donors, the Red Cross estimated that its deferral policy would be less disruptive than FDA expects, resulting in a loss of about 4 percent of active donors.³⁵

Nationwide Blood Supply Can Likely Compensate for Donor Losses Resulting from New Policies

The overall growth in the U.S. blood supply in recent years and the demonstrated ability of particular blood suppliers to increase collections indicate that the blood industry as a whole can compensate for donor losses from the new vCJD donor deferrals. First, as we noted earlier, the long-term trends in blood collections are positive, and collections have increased substantially over the last 5 years. For example, prior to September 11, NBDRC had estimated that the nation's blood collections for 2001 would exceed the number of units transfused in 2000 by more than 7 percent. Second, the Red Cross was able to increase its blood collections in early 2001—collections were 2 percent higher in the first 7 months of 2001 compared with 2000—despite the April 2000 implementation of FDA's initial deferral guidance and Red Cross's adoption of a new technique to measure red blood cell levels that disqualified 6 percent of potential donors at its centers.³⁶ Red Cross reported collections in July 2001 that were 8 percent higher than for the same period in 2000. Finally, before September 11, NYBC was able to increase its collections at a 12 percent annual rate over the last few years. We believe that this large and sustained increase in

³⁴A 1999 donor survey of multiple blood collection centers amassed the travel histories of approximately 9,500 donors, and FDA used these data to estimate donor losses from the revised deferral policies.

³⁵On the basis of a review of military personnel records, DOD expects to defer about 18 percent of active duty personnel and 17 percent of their dependents as a result of the new deferrals. DOD expects greater losses because of the large number of military personnel who have been stationed in Europe.

³⁶In August 2000, the Red Cross began measuring each potential donor's hematocrit, or red blood cell level, by taking a small blood sample from a finger instead of from an earlobe. According to the Red Cross, the earlobe sampling method overestimates hematocrit levels by 5 percent. Therefore, some potential donors who would have had adequate hematocrit measurements under the old system were disqualified with the new, more accurate, finger-prick blood measurements.

collections for an individual blood bank that was previously known for a chronic shortfall in collections indicates that blood centers will be able to increase collections in response to the new vCJD donor policy.

Despite the adequacy of the nation's blood supply, individual blood collection centers with a relatively large proportion of donors who have traveled to Europe will be more severely affected than others by the new exclusion policies. If these centers cannot find ways to increase local blood collections, they, or the hospitals they serve, will need to purchase blood from suppliers with an adequate inventory. The Red Cross donor survey found that its most affected regions would lose 5 percent of their donors, compared with 2 percent for the regions least affected. Blood centers in coastal urban areas that have a greater number of donors who have traveled overseas could experience deferral rates greater than 5 percent. Some other centers serving areas with many people who have lived overseas, such as DOD-affiliated personnel, will also be disproportionately affected. NYBC will probably be affected the most under FDA's new deferral policy. NYBC currently imports about 25 percent of its supply from three European blood centers that collect blood under NYBC's FDA license. NYBC will be unable to import blood from these centers when the second phase of FDA's new deferral policy takes effect on October 31, 2002. Prior to September 11, NYBC was confident that it could compensate for the loss of supply from its European centers because it had substantially increased domestic collections during the last few years. However, NYBC now claims that its local donor base has decreased by about 25 percent since September 11 because many of the companies that participated in its blood drives were directly affected by the terrorist attacks and have reduced employment levels in the city. To compensate for the loss of blood from its European centers, NYBC has contracted to purchase blood from many other domestic blood suppliers, including the Red Cross and blood banks affiliated with ABC.

Recent Blood Price Increases are Partly the Result of New Measures to Improve Blood Safety

Although blood is collected primarily from unpaid volunteers, blood banks incur costs from collecting, processing, and testing donated blood. To recover these costs, blood banks sell the processed blood to hospitals. The prices paid by different hospitals and prices for different types of blood vary substantially. Furthermore, the average price of blood has risen sharply since 1998. One of several contributing factors to these price increases has been the introduction of new blood safety measures. For example, leukoreduction adds about \$30 to the price of a unit of blood.

Although not widespread in 1998, leukoreduction is performed on most blood sold in the United States today.

Price of Blood Varies Widely

To recover the costs of collecting, processing, and testing, blood banks sell their processed blood. Because hospitals and suppliers negotiate the price and quantity of blood to be delivered, prices vary considerably depending on the size and location of the hospital and the type of blood purchased. Larger hospitals, and those in areas with more than one blood center, may sometimes pay less than other hospitals. For example, one of the hospitals we contacted told us that its average price for a unit of blood was \$135, while another hospital told us that its average price was \$200. Similarly, ABC told us that the list prices charged by its centers for a unit of leukoreduced red blood cells in September 2001 averaged \$143, but one-quarter of the centers charged \$124 or less and one-quarter charged at least \$160. In addition, prices for units of the most useful blood types can be much higher than those for blood types that are in less demand. For example, in 2001, one independent blood center charged its non-sole-source customers more than \$260 dollars for a unit of type O-negative blood but less than \$60 for a unit of AB-positive blood.

Price of Blood Has Increased Sharply in Recent Years

The average price of a unit of blood sold to U.S. hospitals has increased substantially since 1998. Both the Red Cross and ABC-affiliated blood banks increased average prices by more than 50 percent from 1998 through 2001 (see table 1). The Red Cross made additional price increases of 10 to 35 percent for different types of blood at the beginning of its fiscal year 2002 (which began July 1, 2001) that are not reflected in the table.

Table 1: Average Red Blood Cell Prices per Unit, 1998-2001

Year^a	ABC^b	Red Cross
1998	\$77	\$84
1999	\$85	\$89
2000	\$96	\$109
2001	\$127	\$129
Percentage change, 1998-2001	65%	54%

^aABC averages are for calendar years; Red Cross averages are for its fiscal years, which begin July 1.

^bAverage prices for the Red Cross include both leukoreduced and nonleukoreduced units. The ABC figures from 1998 through 1999 include only nonleukoreduced blood. The ABC figures for 2000 and 2001 include both leukoreduced and nonleukoreduced blood. The ABC price for 2001 is based on a GAO calculation.

Source: ABC and Red Cross.

New Processing and Testing Steps Have Contributed to Price Increases

Blood suppliers gave us several reasons for the recent price increases. They claimed that blood prices previously had been too low to support their blood collection and processing infrastructure. For example, according to a Red Cross official, the Red Cross revenue from blood services could not cover its costs associated with transporting blood, training and retaining staff, and obtaining and using new technologies. In addition, the Red Cross told us that it increased prices in order to hire additional staff needed to comply with the terms of its consent decree with FDA.

New processing and testing steps that improve blood safety also have contributed to the price increases. The most substantial change is leukoreduction, the removal of white blood cells from blood. For example, the average nationwide price of a unit of blood from the Red Cross in fiscal year 2001 was \$104 for nonleukoreduced blood and \$136 for leukoreduced blood. The percentage of units that have been leukoreduced has risen sharply in recent years. The Red Cross reported that the percentage of its blood that was leukoreduced went from zero in 1998 to almost 80 percent in 2000 and to 95 percent at the beginning of 2002. ABC estimates that by December 2002 about 57 percent of the blood supplied by its affiliated blood centers will be leukoreduced. Similarly, a study commissioned by AABB has estimated that NAT added about \$8 to the price of a unit of blood in 2000. Most blood supplied in the United States now undergoes NAT.

Conclusions

The nation's blood supply remains generally adequate, and collectively America's blood banks probably will be able to compensate for donors lost as a result of the new vCJD donor deferral policies. Lessons learned from blood collection and usage after the September 11 terrorist attacks have prompted efforts to improve how blood suppliers respond to public health emergencies. However, questions about the adequacy of the blood supply will continue because the demand for blood is increasing and because new testing procedures and donor deferral policies that arise in response to emerging disease threats may continue to reduce the pool of potential donors. For these reasons, there is a clear need for comprehensive, long-term monitoring of the blood supply.

Agency Comments

We asked for comments on a draft of this report from HHS and DOD. HHS responded that it had no general comments. DOD concurred with our findings (see app. III). Both HHS and DOD made additional technical comments that we have incorporated where appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its issue date. At that time, we will send copies to the Secretary of Health and Human Services, the Secretary of Defense, and other interested parties. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

Please contact me at (202) 512-7119 if you have any questions about this report. Another GAO contact and staff acknowledgments are listed in appendix IV.

Sincerely yours,



Janet Heinrich
Director, Health Care—Public Health Issues

Summary of vCJD Donor Deferrals

	Criteria for donor deferrals	Estimated donor loss	Estimated risk reduction	Status
First FDA deferral guidance	<ul style="list-style-type: none"> Cumulative travel to United Kingdom, from 1980-1996, of 6 months or more 	FDA estimated 2.2%	68%	Implemented April 2000
New FDA donor deferral guidance^a	<ul style="list-style-type: none"> Cumulative travel to United Kingdom, 1980-1996, of 3 months or more Cumulative travel to Europe, 1980-present, of 5 years or more DOD personnel stationed in Europe, 1980-1990, for cumulative period of 6 months or more^b Anyone who received a transfusion in the United Kingdom, 1980-present Anyone having received bovine insulin prepared in the United Kingdom since 1980 	FDA estimated 5%	91% in total (23% from new deferral criteria)	Scheduled to be implemented in two phases: the first on May 31, 2002; the second by Oct. 31, 2002
American Red Cross deferral policy	<ul style="list-style-type: none"> Cumulative travel to United Kingdom, 1980-present, of 3 months or more Cumulative travel to Europe, 1980-present, of 6 months or more Anyone who received a transfusion in the United Kingdom, 1980-present 	FDA estimated 8%; Red Cross estimated 4%	92% in total	Implemented October 15, 2001
DOD deferral policy	<ul style="list-style-type: none"> Cumulative travel to United Kingdom, 1980-1996, of 3 months or more DOD-affiliated personnel with travel to countries with a risk of BSE, 1980-1996, of 5 months or more DOD-affiliated personnel with travel to countries with a risk of BSE, 1997-present, of 5 years or more Others with travel to countries with a risk of BSE, 1980-present, more than 5 years Anyone having a transfusion in the United Kingdom, 1980-present Anyone having received bovine insulin prepared in the United Kingdom since 1980 	18% from active duty personnel; 17% from dependents	Not estimated	Implemented October 29, 2001

^aFDA recommends deferral of source plasma donors with 5 years cumulative travel in France from 1980 to the present. However, FDA's new deferral policy for 5 years exposure elsewhere in Europe does not apply to source plasma. In part, this reflects FDA's belief that, on the basis of the results of experiments conducted by plasma product manufacturers, the manufacturing process for plasma-derivative products minimizes the risk of transmission of vCJD through plasma. In addition, FDA is concerned that disqualifying plasma donors by extending the deferral policy to them may threaten the sufficiency of the plasma supply. The Plasma Protein Therapeutics Association (PPTA) conducted a donor travel survey in 30 plasma collection centers and found that donor losses could range from 0 to 13 percent, with the greatest losses occurring at centers located near military bases. The overall donor loss was estimated to be about 3.5 percent. A survey conducted by one of PPTA's member companies suggested that overall donor loss would be closer to 5 percent. PPTA also expected that a ban on the use of plasma in the United States from European donors, as would occur if the vCJD deferral policy was applied to plasma, would adversely affect an already tight supply of plasma-derived therapeutics, causing some countries to reject European plasma and thus putting extreme pressure on other sources of plasma, such as the United States, to meet global demand.

Appendix I
Summary of vCJD Donor Deferrals

^bFDA's deferral for military personnel differs according to the geographic location of the individual's service in Europe. FDA recommends the deferral of blood donations from former or current U.S. military and civilian military personnel and their dependents who resided at U.S. military bases in Germany, United Kingdom, Belgium and the Netherlands for 6 months or more from 1980 through 1990, or who resided at U.S. military bases in Greece, Turkey, Spain, Portugal, and Italy for 6 months or more from 1980 through 1996.

Source: FDA, Red Cross, and DOD data.

Risk of vCJD Infection through Blood Transfusion Is Unknown

Transmission of vCJD by human blood or plasma has not been demonstrated, and no laboratory or epidemiological studies have shown that blood from donors infected with vCJD carries the disease. For example, at least 20 people in the United Kingdom have received blood or blood components from donors who later developed vCJD. Although relatively little time has passed, none of the recipients of the blood have developed vCJD. Studies of patients with vCJD and a prior history of receiving blood transfusions have not revealed any cases of vCJD among the donors involved.

Nonetheless, laboratory experiments point to a theoretical risk of transmission of vCJD through blood. For example, tissue samples from vCJD patients have found the agents that cause vCJD, protein molecules known as prions, in human lymph tissue, such as the tonsils and the spleen. Since white blood cells known as B lymphocytes also circulate through these tissues and are potentially involved in the pathology of vCJD, researchers suggest that these circulating lymphocytes may carry infectivity in blood.³⁷ Experiments with animals have shown that blood infected with vCJD-like agents contain low-levels of infectivity. In addition, one group of researchers has recently demonstrated that BSE can be experimentally transmitted between sheep by blood transfusion.³⁸ However, results from this experiment may not be representative of the human manifestation of vCJD.

³⁷A.F. Hill and others, "Investigation of Variant Creutzfeldt-Jakob Disease and Other Human Prion Diseases with Tonsil Biopsy Samples," *Lancet*, vol. 353, no. 9148 (1999), pp. 183-189.

³⁸F. Houston and others, "Transmission of BSE By Blood Transfusion in Sheep," *Lancet*, vol. 356, no. 9234 (2000), pp. 999-1000.

Epidemiological Predictions

Researchers are limited in the conclusions they can make concerning vCJD and blood safety, and in predicting the future number of vCJD cases. Important variables in determining the probability of BSE transmission to humans, such as route of exposure, genetic susceptibility, and dose, remain unproven. Further, the incubation period for vCJD is unknown but is probably many years. Citing the current modest number of additional deaths in the United Kingdom caused by vCJD (there were 28 confirmed or probable vCJD deaths in the United Kingdom in 2000 and 20 in 2001), some researchers suggest that the epidemic will not reach the hundreds of thousands once thought possible. As a result, the projected number of total cases has been revised downward to just a few hundred or few thousand cases, with fewer than 100 new cases occurring per year.³⁹ Such revised estimates are based on varying assumptions regarding the average incubation period and when individuals were infected.⁴⁰

The ambiguity of the scientific evidence regarding vCJD transmission through blood is reflected in the divided vote of FDA's advisory committee (the Transmissible Spongiform Encephalopathies Advisory Committee, or TSEAC) in favor of the expanded donor deferral. The committee voted 10 to 7 in June 2001 to move forward with the proposed changes, but several members expressed concern about the expanded deferral's impact on blood availability, the effectiveness of current efforts to control human exposure to BSE in the United Kingdom, and the reliability of European surveillance data.

Detection Tests for vCJD under Development

The scientific uncertainties surrounding vCJD would be greatly reduced if a diagnostic test existed to confirm the presence or absence of vCJD in human blood. While tests are being developed, it could be some time before an accurate test will be available to screen blood for the vCJD agent. Tests do exist to detect vCJD prions in some human tissues, such as brain tissue, tonsils, and appendixes, but no suitable tests are available to detect vCJD infections in blood. Prions are different than viral and bacterial

³⁹J.N. d'Aignaux and others, "Predictability of the UK variant Creutzfeldt-Jakob Disease Epidemic," *Science*, vol. 5547, no. 294 (2001), pp. 729-31.

⁴⁰P. Brown, "Bovine Spongiform Encephalopathy and Variant Creutzfeldt-Jakob Disease," *British Medical Journal* vol. 322, No. 7290 (2001), pp. 841-44, and Rebecca Love, "Has the Variant Creutzfeldt-Jakob Disease Epidemic Hit Its Peak?" *Lancet*, vol. 358, no. 9291 (2001), p. 1432.

Appendix II
Risk of vCJD Infection through Blood
Transfusion Is Unknown

pathogens, which contain nucleic acids. Some pathogens and viruses trigger the human body to release specific antibodies, which may be detected in the blood. For example, both HIV and hepatitis elicit antibodies in the blood that can be detected in a blood test. At this point, most scientists believe that prions, such as those involved in vCJD, do not contain nucleic acids and do not elicit the production of antibodies. This poses a challenge in designing a blood test, which must be 100,000 times as sensitive as assays that already exist for detecting prions in tissues. If a test were approved, it would be required to be extremely sensitive to minimize the possibility of false positives, which would unnecessarily defer from donating blood many individuals who did not actually have the vCJD agent in their blood.

Comments from the Department of Defense



THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

JUL 17 2002

Ms. Janet Heinrich
Director, Health Care-Public
Health Issues
U.S. General Accounting Office
Washington, D.C. 20548

Dear Ms. Heinrich:

This is the Department of Defense (DoD) response to the GAO draft report GAO-02-747, "PUBLIC HEALTH: Blood Supply Generally Adequate Despite New Donor Restrictions," dated June 14, 2002 (GAO Code 290076).

In general, the DoD concurs with the overall GAO draft report. Functional experts from the Department, the Surgeons General, and the Armed Services Blood Program Office have also reviewed the report and concur. Their specific technical comments and recommendations on the draft report are incorporated into our response.

Please feel free to direct any questions on this reply to my project officer, Major Henri Hammond (functional), at (703) 681-1724 or Mr. Gunther J. Zimmerman (GAO/IG Liaison) at (703) 681-7889, extension 1229.

Sincerely,

A handwritten signature in cursive script that reads "William Winkenwerder, Jr.".

William Winkenwerder, Jr., MD

Enclosures:
As stated

GAO Contact and Staff Acknowledgments

GAO Contact

Martin T. Gahart, (202) 512-3596

**Staff
Acknowledgments**

The following staff made important contributions to this work: Carolina Morgan, Sharif Idris, Mark Patterson, and Elizabeth Morrison.

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